

## REMARKS

### Status of the Claims

By virtue of the Listing of Claims presented herein, claims 30-40 are pending. Claims 1-29 and 41-51 have withdrawn as directed to non-elected subject matter.

Claim 30 has been amended to recite that the recited ob polypeptide has an amino acid sequence represented by SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO5, SEQ ID NO:6, or an immunogenic fragment of such sequences. Basis for the amendment may be found, for example: in claims 17 through 20 as originally filed, which disclose that an ob polypeptide may be selected from an amino acid sequence represented by SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO5, and SEQ ID NO:6; and paragraph [0020] of the publication of the instant patent application, publication number US 2004/0214214 (referred to throughout remainder of this paper), which discloses that the ob polypeptides, and, e.g., active fragments and conserved variants thereof, may be employed; e.g., in the preparation of antibodies against such materials.

Claim 36 has been amended to recite that after a determination is made as to the amount of reaction complexes formed by performing step B., a step C. is performed, in which a comparison is made between the amount determined in step B. and a known amount in order to evaluate the level of ob polypeptide in the biological sample. Basis for the amendment may be found, for example, at: paragraphs [0022]; [0086]; [0128] through [0129]; [0137]; and references cited throughout; which are incorporated in their entirety, and which collectively disclose procedures by which a detected amount of a component of biological sample may be compared with a known amount of the component for evaluatory purposes, as recited in the present claim as amended.

Thus, no new matter has been introduced by the amendments to the claims.

### Election/Restrictions

The Examiner's acknowledgement of Applicant's election, with traverse, of Group V is acknowledged. The Examiner's agreement that Group V and Group VI should be rejoined and examined together in the instant application is also acknowledged. Accordingly, Applicant has withdrawn claims 1-29 and 41-51, as reflected in the attached Listing of Claims, without

prejudice or disclaimer to the right to pursue non-elected subject matter in one or more continuation or divisional applications.

Priority

The Examiner states that one or more conditions for receiving benefit of an earlier filing date under 35 U.S.C. § 121 in the instant application have not been met. Specifically, the Examiner states that a reference to prior applications from which benefit of priority is entitled in the instant application must be inserted as the first sentence of the specification of the application or in an application data sheet if the Applicant intends to rely of the filing date of such prior applications.

Applicant submits that the amendment to the specification provided herein fulfills the requirements for perfecting a claim for benefit of priority of (a) prior application(s) under 35 U.S.C. § 121. Applicant further submits that neither a petition, surcharge, nor a statement under 37 C.F.R. § 1.78(a)(2) or § 1.78(a)(5) and 37 C.F.R. § 1.17(t) is required, insofar as a reference to prior applications was previously submitted in an oath or declaration and in a Utility Patent Application Transmittal (Form PTO/SB/05) within the time period set forth in 37 C.F.R. 1.78(a).

As evidence of the submittals, Applicant provides herewith as the following as EXHIBITS 1, 2, and 3, respectively: a copy of the Form PTO/SB/05, executed February 17, 2004, in which Applicants declared that the instant application is a divisional application of prior application No. 09/316,393 (see box 18.); a copy of the Declaration that was filed in prior application No. 09/316,393 as well as in the instant application, which was fully executed on March 3, 1995, and which declares that the subject matter which is/was claimed and for which a patent is/was sought in prior application No. 09/316,393 and in the instant application, respectively, was disclosed in the Specification which was filed as Application Serial No. 08/292,345 on August 17, 1994; and a copy of the first Filing Receipt that issued in the instant case, which was mailed June 15, 2004, and which acknowledges the patent Office's recognition of the priority benefit claim of the instant application as a divisional (DIV) of prior application No. 09/316,393 (now U.S. Patent 6,734,160, which is a divisional (DIV) of prior application No. 08/292,345 (now U.S. Patent No. 6,001,968).

Accordingly, neither the petition, statement, nor surcharge under 37 C.F.R. § 1.78(a) under 37 C.F.R. § 1.17(t) is required. Additionally, Applicant provides reference to the prior applications by way of the below-provided amendment to the first sentence of the specification in compliance with 37 C.F.R. § 1.78(a). Accordingly, Applicant submits that the conditions for receiving benefit of earlier filing date under 35 U.S.C. § 121 of prior applications 09/316, 393 and 08/292,245 have been met.

#### Information Disclosure Statement

Applicant apologizes for the apparently non-compliant condition of the Information Disclosure Statement submitted on February 17, 2004. It is respectfully submitted that the Applicant's submission of the Information Disclosure Statement and associated papers represented a *bona fide* attempt on the part of the Application to fully comply with the requirements of 37 C.F.R. §§ 1.56 and 1.98. Applicant further understands that the Examiner, while noting the apparently non-compliant nature to the Information Disclosure Statement and associated papers, has nonetheless received and considered the Statement and associated papers, and entered them into the record of the instant case. Applicants thank the Examiner for consideration of the previously submitted Information Disclosure Statements.

#### Specification

The Examiner has objected to the Abstract as originally filed, alleging that it is not a ““concise”” statement of the technical disclosure of the patent, and that the Abstract “should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.” Without acquiescing to the Examiner's allegations concerning the Abstract as originally filed, Applicant submits that Abstract as amended herein is compliant with the requirements outlined in MPEP § 608.01(b) Basis for the amendment may be found, e.g., throughout the specification as originally filed, including the abstract and claims as originally filed. Thus, the amendment does not constitute new matter, and does not limit the scope of the subject matter for which protection is, or may be, sought, or to which Applicant is entitled.

The Examiner has also objected to the Title as originally filed, asserting that the “title of

the invention is not descriptive,” and that a new title that is “clearly indicative of the invention to which the claims are directed,” is required. Applicant respectfully submits that the objection is unwarranted at this time insofar as no indication of allowable subject matter has been provided. Applicant respectfully requests deferral of the objection until such time that such a determination is provided, so that the propriety of the objection can be finally and properly assessed. Applicant submits that this response constitutes a full reply to the objection and further constitutes a *bona fide* attempt to advance the application to final action in accordance with the requirements of 37 C.F.R. § 1.111(b) .

#### Claim Rejections

Applicants have carefully considered the points raised in the outstanding Office Action and believe that the Examiner’s concerns have been addressed as described herein, thereby placing this case into condition for allowance.

#### Rejection under 35 U.S.C. § 112, second paragraph:

Claims 30-40 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner alleges that there is “no recitation of what ob ‘polypeptide’ encompasses”, and since the specification allegedly does not define ‘ob polypeptide’ such that one of ordinary skill in the art would know that they were possession of an antibody that bound to it.

Without acquiescing to the Examiner’s assertions, and as mentioned above, Applicant has amended claim 30 to recite that the recited ob polypeptides each have an amino acid sequence represented by SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, or an immunogenic fragment thereof. The amendment is made without prejudice or disclaimer to the right to pursue omitted or non-elected subject matter in one or more continuation or divisional applications.

Claim 36 has also been rejected under 35 U.S.C. § 112, second paragraph, as allegedly “being incomplete for omitting essential steps, such omission amounting to a gap between steps.” The Examiner further states that “[t]he omitted steps are: a comparison step to a known

concentration to evaluate the level of ob polypeptide in a sample.”

Without acquiescing to the Examiner’s assertions, and as mentioned above, Applicant has amended claim 36 to recite after step B. a comparing step C.: comparing the amount determined in step B. with an amount of ob polypeptide in a control sample in order to evaluate the level of ob polypeptide in the biological sample.

Applicant submit that the requirements of 35 U.S.C. § 112, second paragraph, are met with respect to claims 30-40 as amended herein. Accordingly, the rejection should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

*Claims 37-40*

Claims 37-40 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the examiner asserts that the claimed methods are not described in the instant specification insofar as there is allegedly “no description in the instant specification which correlates any disease or condition with altered levels of ob polypeptide.” The Examiner further asserts that the instant specification “fails to describe any normal levels of ob polypeptide in an individual, and therefore, there is no basis for establishing what would be normal,” and thus concludes that “one of ordinary skill in the art cannot make any reasonable determination as to the presence of a disease based solely on an increase or decrease in ob polypeptide levels.” We disagree.

The instant specification, discloses, for example, that: (1) obesity is known to be associated with other medical co-morbidities, including hypertension, elevated blood lipids, and type II diabetes (see, e.g., paragraph [0003]); (2) animal (e.g., mouse) models for obesity display, for example, alterations in metabolism resembling those seen in type II diabetes in man, as well as a predisposition towards excessive food intake and decreased energy expenditure (see, e.g., paragraphs [0007] and [0008]); (3) studies of two animal models for obesity (e.g., the ob/ob mouse strain and the db/db mouse strain) demonstrate that lack of a circulating factor and/or its activity, determined and disclosed in the instant application by Applicants to be ob polypeptide, accounts for the phenotype of these models (see, e.g., paragraphs [0008] through [0010]; and (4)

whereas low levels of ob polypeptide and/or its activity correlate with obesity and diabetes and their co-morbidities, weight loss associated with, for example, cancer, HIV infection, and other nutritional disorders is predicted to correlate with elevated levels of ob polypeptide (see, e.g., paragraphs [0158], [0159], and [0167]). Thus, contrary to the Examiner's assertions, there is ample disclosure in the instant application concerning correlation between altered ob polypeptide levels and/or activity and prevalence of numerous diseases known to be associated with obesity and other nutritional disorders.

With regard to the Examiner's insistence that the instant specification "fails to describe any normal levels of ob polypeptide in an individual, and therefore, there is no basis for establishing what would be normal," and thus concludes that "one of ordinary skill in the art cannot make any reasonable determination as to the presence of a disease based solely on an increase or decrease in ob polypeptide levels, Applicant submits that it was well within the purview of the skilled artisan, once such artisan is armed with knowledge concerning: the identity and biological activity of ob polypeptide (see, e.g., entire specification throughout, paragraphs [0158] and [0159] in particular); methods for detecting the presence or absence of ob polypeptide (see, e.g., paragraphs [0116] through [0139]); and a correlation between the presence or absence of ob polypeptide and the presence or absence of a disease or condition in an individual (see, e.g., paragraphs [0008] through [0010], [0158], [0159], and [0167]); to measure levels of such ob polypeptide in individuals known to have or suspected to have such a correlative disease or condition, and to compare such measured levels with levels obtained from individuals who do not have or are not suspected to have the disease or condition (i.e., "normal" individual. Such comparisons to "normal" individuals constitute negative controls, and as such are routine in the art. Thus, again contrary to the Examiner's assertions, the disclosure in the instant application is sufficient to convey to the skilled artisan that Applicant was in possession of the instantly claimed methods.

#### *Claims 38-40*

The Examiner has also rejected claims 38-40 as allegedly failing to comply with the enablement requirement, insofar as the specification allegedly does not enable a "therapeutic

treatment of a disease since no disease has been associated with elevated or decrease levels of ob polypeptide.” The Examiner further insists that “[w]ithout a correlation or nexus between ob polypeptide levels and any one of [the claimed] conditions, the claims are not enabled.”

For the reasons provided above, at least, Applicant has provided ample disclosure of such “nexus” between the recited diseases and conditions and lettered ob polypeptide levels.

In light of the foregoing, there can be no doubt that the instant claims enjoy ample and adequate written description support, and are sufficiently enabled, such that the requirements under Section 112 paragraph are met. Accordingly, the Section 112 rejections are in error and should be withdrawn, and the instant claims allowed.

Applicants believe that all issues raised in the Office Action have been properly addressed in this response and in the amendments to the claims as shown in the attached Listing of Claims. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants’ representative at the telephone number below.

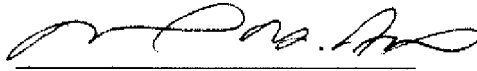
#### **CONCLUSION**

A petition for a three-month extension of time is attached.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Deposit Account 19-4293 referencing Docket No. 16454.0002 D1. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Deposit Account 19-4293.

Respectfully submitted,

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